**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

| | | |
|---|---|---|
| ALZA CORPORATION and JANSSEN PHARMACEUTICALS, INC., | ) | |
| Plaintiffs, | ) | |
| v. | ) | Civil Action No. _____ |
| | ) | **REDACTED PUBLIC VERSION** |
| AMNEAL PHARMACEUTICALS OF NEW YORK, LLC and AMNEAL PHARMACEUTICALS LLC, | ) | |
| Defendants. | ) | |

## COMPLAINT

In this patent infringement action, Plaintiffs ALZA Corporation ("ALZA") and Janssen Pharmaceuticals, Inc. (collectively "Plaintiffs"), for their complaint against Defendants Amneal Pharmaceuticals of New York, LLC ("Amneal Pharms. NY") and Amneal Pharmaceuticals LLC ("Amneal Pharms. LLC") (collectively, "Amneal"), allege as follows:

## NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, in response to, *inter alia*, the submission by Amneal of Abbreviated New Drug Application ("ANDA") No. 207515, [redacted] with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of CONCERTA® prior to the expiration of U.S. Patent No. 8,163,798 ("the '798 patent") and U.S. Patent No. 9,144,549 ("the '549 patent").

## PARTIES

2. Plaintiff ALZA is a Delaware corporation, having its principal place of business at 700 Eubanks Drive, Vacaville, California 95688.

**REDACTED PUBLIC VERSION**

3. Plaintiff Janssen Pharmaceuticals, Inc. ("Janssen") is a Pennsylvania corporation, having a place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

4. On information and belief, Defendant Amneal Pharms. LLC is a limited liability company organized under the laws of the State of Delaware and has a place of business at 400 Crossing Boulevard, Bridgewater, NJ 08807.

5. On information and belief, Defendant Amneal Pharms. NY is a limited liability company organized under the laws of the State of Delaware and has a place of business at 50 Horseblock Road, Brookhaven, NY 11719.

6. On information and belief, Amneal Pharms. NY is a wholly owned subsidiary of Amneal Pharms. LLC.

7. On information and belief, Amneal Pharms. NY and Amneal Pharms. LLC operate together as a single business and present themselves as a cohesive entity. [redacted] As another example, upon information and belief, both entities also share a single website (www.amneal.com), which indicates that the locations of "Amneal Pharmaceuticals" in the United States include locations known to be locations for both Amneal Pharms. NY and Amneal Pharms. LLC.

8. [redacted]

**REDACTED PUBLIC VERSION**

9. On information and belief, Amneal Pharms. NY acted at the direction of, and as an agent on behalf of, and for the benefit of, Amneal Pharms. LLC, in the preparation and submission of ANDA No. 207515, [redacted] and will act at the direction of, and as an agent on behalf of, and for the benefit of Amneal Pharms. LLC in the sale, offer for sale, marketing, distribution, and/or importation of the generic drug product that is the subject of ANDA No. 207515 if the ANDA is approved by the FDA. For example, on August 31, 2016, Plaintiffs received a letter dated August 26, 2016 (the "Notice Letter"), purporting to be notice of Amneal's ANDA No. 207515 and "Paragraph IV" certification(s) required by 21 U.S.C. § 355(j)(2)(B)(i)-(ii) [redacted] and this letter is from Amneal Pharms. LLC.

## JURISDICTION AND VENUE

10. This action for patent infringement arises under 35 U.S.C. § 1 *et seq.* generally, and 35 U.S.C. §§ 271(a), 271(b), 271(c), and 271(e)(2) specifically.

11. This Court has subject matter jurisdiction over this dispute pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

12. On information and belief, Amneal Pharms. NY, together with, and/or on behalf of Amneal Pharms. LLC, formulates, manufactures, packages, markets, distributes, and sells generic pharmaceutical products. On information and belief, those products are marketed, distributed, and sold in the District of Delaware and throughout the United States.

13. On information and belief, Amneal Pharms. NY, together with, and/or on behalf of Amneal Pharms. LLC, is the owner of ANDA No. 207515.

14. On information and belief, Amneal Pharms. NY, together with, and/or on behalf of Amneal Pharms. LLC., submitted ANDA No. 207515, [redacted] to the FDA. [redacted]

**REDACTED PUBLIC VERSION**

[redacted]

15. On information and belief, Amneal Pharms. NY, together with, and/or on behalf of Amneal Pharms. LLC, will market, distribute, and/or sell the generic products that are the subject of ANDA No. 207515, if approved, in the District of Delaware.

16. On information and belief, if approved, doctors and patients will use, in the District of Delaware, the generic products that are the subject of ANDA No. 207515 for the indications found in the approved generic label, [redacted]

17. On information and belief, this Court has personal jurisdiction over Amneal Pharms. NY by virtue of, *inter alia*: (1) its formation as a company under the laws of Delaware; (2) its designation of a registered agent and registered office in Delaware; (3) its prior consent to be sued in Delaware; (4) its systematic and continuous contacts with Delaware; and (5) its course of conduct that is designed to cause the performance of tortious acts that will result in foreseeable harm to Plaintiffs in Delaware.

18. On information and belief, personal jurisdiction over Amneal Pharms. NY is proper because as a Delaware limited liability company, Amneal Pharms. NY resides in the State of Delaware and has purposely availed itself of the privilege of doing business in this State.

19. On information and belief, personal jurisdiction over Amneal Pharms. NY is also proper because Amneal Pharms. NY expressly consented to general personal jurisdiction in the State of Delaware by appointing a Delaware resident as its agent for service of process. On information and belief, the registered agent of Amneal Pharms. NY is The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

**REDACTED PUBLIC VERSION**

20. Personal jurisdiction over Amneal Pharms. NY is also proper because Amneal Pharms. NY has submitted to the personal jurisdiction of the United States District Court for the District of Delaware in numerous actions, including at least: *Forest Labs. Inc. et al v. Lupin Pharms Inc.*, 1-08-cv-00021 (D. Del.); *UCB Inc. v. Amneal Pharms. LLC*, 1-13-cv-01208 (D. Del.); *Forest Labs. Inc. v. Amneal Pharms. LLC*, 1-13-cv-01737 (D. Del.); *Forest Labs., Inc. v. Amneal Pharms. LLC*, 1-14-cv-00508 (D. Del.); *Sanofi v. Amneal Pharms. LLC*, 71-14-cv-00875 (D. Del.); *Forest Labs., LLC f/k/a Forest Labs., Inc. v. Amneal Pharms. LLC*, 1-15-cv-00430 (D. Del.); *Meda Pharms. Inc. v. Amneal Pharms. LLC*, 1-15-cv-00617 (D. Del.); *Forest Labs., LLC f/k/a Forest Labs., Inc. v. Amneal Pharms. LLC*, 1-15-cv-00756 (D. Del.); *Novartis Pharms. Corp. v. Amneal Pharms. LLC*, 1-15-cv-01025 (D. Del.); *AstraZeneca LP v. Amneal Pharms. LLC*, 1-15-cv-01056 (D. Del.); *AstraZeneca Pharms. LP v. Amneal Pharms. LLC*, 1-15-cv-01139 (D. Del.).

21. Personal jurisdiction over Amneal Pharms. NY is also proper because, on information and belief, Amneal Pharms. NY maintains continuous and systematic contacts with the State of Delaware, including the sale and use of Amneal Pharms. NY's products in Delaware, so as to reasonably allow jurisdiction to be exercised over it. On information and belief, Amneal Pharms. NY, either directly or through one or more of its subsidiaries, agents, and/or distributors, sells and/or distributes a substantial volume of its pharmaceutical products in Delaware. For example, on information and belief, Amneal Pharms. NY holds current "Pharmacy – Wholesale" and controlled substance "Distributor/Manufacturer CSR" licenses from the State of Delaware. The active pharmaceutical ingredient found in the generic drug products that are the subject of ANDA No. 207515 is methylphenidate hydrochloride, a controlled substance. Thus, upon information and belief, Amneal Pharms. NY intends to market, distribute, and/or sell the generic products that are the subject of ANDA No. 207515, if approved, in the District of Delaware.

22. This Court has personal jurisdiction over Amneal Pharms. NY by virtue of the fact that by submitting ANDA No. 207515, [redacted]

**REDACTED PUBLIC VERSION**

[redacted] for generic methylphenidate hydrochloride extended-release tablets, Amneal Pharms. NY has, *inter alia*, committed, or aided, abetted, contributed to and/or participated in the commission of, a tortious act of patent infringement that has led to foreseeable harm and injury to a Delaware corporation, Plaintiff ALZA, in Delaware.

23. This Court has personal jurisdiction over Amneal Pharms. NY for the reasons set forth above and for other reasons that will be presented to the Court if such jurisdiction is challenged.

24. On information and belief, this Court has personal jurisdiction over Amneal Pharms. LLC by virtue of, *inter alia*: (1) its formation as a company under the laws of Delaware; (2) its designation of a registered agent and registered office in Delaware; (3) its prior consent to be sued in Delaware; (4) its systematic and continuous contacts with Delaware; and (5) its course of conduct that is designed to cause the performance of tortious acts that will result in foreseeable harm to Plaintiffs in Delaware.

25. On information and belief, personal jurisdiction over Amneal Pharms. LLC is proper because as a Delaware limited liability company, Amneal Pharms. LLC resides in the State of Delaware and has purposely availed itself of the privilege of doing business in this State.

26. On information and belief, personal jurisdiction over Amneal Pharms. LLC is also proper because Amneal Pharms. LLC expressly consented to general personal jurisdiction in the State of Delaware by appointing a Delaware resident as its agent for service of process. On information and belief, the registered agent of Amneal Pharms. LLC is The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801, the same registered agent as Amneal Pharms. NY.

27. Personal jurisdiction over Amneal Pharms. LLC is also proper because Amneal Pharms. LLC has availed itself of the services of the United States District Court for the

District of Delaware in at least *Amneal Pharms. LLC v. GlaxoSmithKline LLC*, 1-16-cv-00300 (D. Del.). Personal jurisdiction over Amneal Pharms. LLC is further proper because Amneal Pharms. LLC has submitted to the personal jurisdiction of the United States District Court for the District of Delaware in numerous actions, including at least: *Forest Labs. Inc. et al v. Lupin Pharms Inc.*, 1-08-cv-00021 (D. Del.); *UCB Inc. v. Amneal Pharms. LLC*, 1-13-cv-01208 (D. Del.); *Forest Labs. Inc. v. Amneal Pharms. LLC*, 1-13-cv-01737 (D. Del.); *Forest Labs., Inc. v. Amneal Pharms. LLC*, 1-14-cv-00508 (D. Del.); *Sanofi v. Amneal Pharms. LLC*, 71-14-cv-00875 (D. Del.); *Forest Labs., LLC f/k/a Forest Labs., Inc. v. Amneal Pharms. LLC*, 1-15-cv-00430 (D. Del.); *Meda Pharms. Inc. v. Amneal Pharms. LLC*, 1-15-cv-00617 (D. Del.); *Forest Labs., LLC f/k/a Forest Labs., Inc. v. Amneal Pharms. LLC*, 1-15-cv-00756 (D. Del.); *Novartis Pharms. Corp. v. Amneal Pharms. LLC*, 1-15-cv-01025 (D. Del.); *AstraZeneca LP v. Amneal Pharms. LLC*, 1-15-cv-01056 (D. Del.); *AstraZeneca Pharms. LP v. Amneal Pharms. LLC*, 1-15-cv-01139 (D. Del.).

28. Personal jurisdiction over Amneal Pharms. LLC is also proper because, on information and belief, Amneal Pharms. LLC maintains continuous and systematic contacts with the State of Delaware, including the sale and use of Amneal Pharms. LLC's products in Delaware, so as to reasonably allow jurisdiction to be exercised over it. On information and belief, Amneal Pharms. LLC, either directly or through one or more of its subsidiaries, agents, and/or distributors, sells and/or distributes a substantial volume of its pharmaceutical products in Delaware. For example, on information and belief, Amneal Pharms. LLC holds current "Pharmacy – Wholesale" and controlled substance "Distributor/Manufacturer CSR" licenses from the State of Delaware. The active pharmaceutical ingredient found in the generic drug products that are the subject of ANDA No. 207515 is methylphenidate hydrochloride, a controlled substance. Thus, upon information and belief, Amneal Pharms. NY intends to market, distribute, and/or sell the generic products that are the subject of ANDA No. 207515, if approved, in the District of Delaware.

**REDACTED PUBLIC VERSION**

29. This Court has personal jurisdiction over Amneal Pharms. LLC by virtue of the fact that by submitting ANDA No. 207515, [redacted] for generic methylphenidate hydrochloride extended-release tablets, Amneal Pharms. LLC has, *inter alia*, committed, or aided, abetted, contributed to and/or participated in the commission of, a tortious act of patent infringement that has led to foreseeable harm and injury to a Delaware corporation, Plaintiff ALZA, in Delaware.

30. This Court has personal jurisdiction over Amneal Pharms. LLC for the reasons set forth above and for other reasons that will be presented to the Court if such jurisdiction is challenged.

31. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

## GENERAL ALLEGATIONS

32. On April 24, 2012, the United States Patent and Trademark Office ("USPTO") issued U.S. Patent No. 8,163,798. A true and correct copy of the '798 Patent is attached hereto as Exhibit A.

33. Plaintiffs own all rights, title and interest in the '798 Patent, including all rights needed to bring this action in Plaintiffs' names.

34. Plaintiff ALZA is the current assignee of the '798 Patent.

35. On September 29, 2015, the USPTO issued U.S. Patent No. 9,144,549. A true and correct copy of the '549 Patent is attached hereto as Exhibit B.

36. Plaintiffs own all rights, title and interest in the '549 Patent, including all rights needed to bring this action in Plaintiffs' names.

37. ALZA is the current assignee of the '549 Patent.

38. ALZA manufactures the drug product covered by the FDA approved New Drug Application ("NDA") No. 21-121 and marketed under the registered tradename

**REDACTED PUBLIC VERSION**

CONCERTA®, the active ingredient of which is methylphenidate hydrochloride ("CONCERTA" or "the CONCERTA® drug product"), in the United States. The CONCERTA® drug product is an orally administered tablet dosage form that operates by an osmotic drug delivery mechanism.

39. Plaintiff Janssen Pharmaceuticals, Inc. holds NDA No. 21-121 for CONCERTA.

40. Marketing of CONCERTA® is authorized in four dosage strengths (*i.e.*, 18 mg, 27 mg, 36 mg, and 54 mg) by NDA No. 21-121.

41. CONCERTA® is currently approved for the treatment of Attention Deficit Hyperactivity Disorder ("ADHD").

42. CONCERTA® is covered by one or more claims of the '798 Patent and/or the '549 Patent, which are listed in connection with CONCERTA® in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") as patents "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug" CONCERTA®. *See* 21 U.S.C. § 355(b)(1).

43. On information and belief, Amneal submitted ANDA No. 207515, [redacted] to the FDA seeking approval to market generic copies of the 18 mg, 27 mg, 36 mg, and 54 mg dosage strengths of the CONCERTA® drug product (the "ANDA Products") prior to the expiration of the '798 Patent and/or the '549 Patent.

44. On information and belief, Amneal has represented that the Reference Listed Drug ("RLD") of its ANDA No. 207515 is CONCERTA®.

45. [redacted]

**REDACTED PUBLIC VERSION**

[redacted]

46. On information and belief, ANDA No. 207515, [redacted] seeks approval to market the ANDA Products for use in the treatment of ADHD.

47. On information and belief, Amneal seeks approval for a generic label that indicates that the ANDA Products are indicated for use in the treatment of ADHD.

48. On information and belief, if ANDA No. 207515, [redacted] is approved by the FDA, Amneal will, prior to the expiration of the '798 Patent and/or the '549 Patent, begin making, selling, offering for sale, marketing, distributing, and/or importing the ANDA Products, and doctors and patients will use the ANDA Products for the indications found in the approved generic label.

49. Pursuant to FDA regulation 21 C.F.R. § 314.94, the ANDA Products must have the same active ingredient, route of administration, dosage form, and dosage strengths as CONCERTA® and must be bioequivalent to CONCERTA®.

50. [redacted]

51. Amneal has represented that it has included in ANDA No. 207515, [redacted] a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging, *inter alia*, that the '798 Patent and the '549 Patent are invalid, that claims 8 and 10 of the '798 Patent are not infringed, and that claims 6, 16, 19, and 26 of the '549 Patent are not infringed.

52. On or about August 31, 2016, Plaintiffs received the Notice Letter. The Paragraph IV certification(s) contained therein alleged, *inter alia*, that the '798 Patent and '549

**REDACTED PUBLIC VERSION**

Patent are invalid, that claims 8 and 10 of the '798 Patent are not infringed, and that claims 6, 16, 19, and 26 of the '549 Patent are not infringed.

53. This action is being commenced within forty-five days of the date of receipt of the Notice Letter.

54. On information and belief, Amneal made the decision to and did submit ANDA No. 207515, [redacted] and "Paragraph IV" certification(s).

55. On information and belief, Amneal was necessarily aware of the '798 Patent and the '549 Patent when it submitted ANDA No. 207515, [redacted] and submitted "Paragraph IV" certification(s) to the FDA in ANDA No. 207515.

56. On information and belief, Amneal did not have an adequate good-faith basis for submitting the "Paragraph IV" certification regarding the '798 Patent or the '549 Patent accompanying its ANDA No. 207515, [redacted]

57. Pursuant to 35 U.S.C. § 271(e)(2)(A), Amneal's submission of ANDA No. 207515, [redacted] seeking FDA approval to market the ANDA Products, is an act of infringement of one or more claims of the '798 Patent and the '549 Patent entitling Plaintiffs to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of the FDA's approval of ANDA No. 207515 be a date which is not earlier than the expiration date of the '798 Patent and the '549 Patent, including any extensions of those dates.

58. The FDA approved label for CONCERTA® indicates that CONCERTA® includes an immediate release drug component of methylphenidate hydrochloride and a sustained or extended release drug component of methylphenidate hydrochloride.

**REDACTED PUBLIC VERSION**

59. The FDA approved label for CONCERTA® also indicates that the "drug release rate from the system increases with time over a period of 6 to 7 hours…."

60. The sustained or extended release drug component of CONCERTA® releases drug at an ascending release rate over at least three hours following administration. *E.g.*, Fig. 3 of the '798 patent and '549 patent.

61. The FDA approved label for CONCERTA® also states that "[f]ollowing administration of CONCERTA, plasma methylphenidate concentrations increase rapidly, reaching an initial maximum at about 1 hour, followed by gradual ascending concentrations over the next 5 to 9 hours…."

62. The FDA approved label for CONCERTA® also indicates that CONCERTA® "uses osmotic pressure to deliver methylphenidate HCl at a controlled rate."

63. [redacted]

64. [redacted]

65. [redacted]

66. [redacted]

**REDACTED PUBLIC VERSION**

[redacted]

67. [redacted]

68. [redacted]

69. On information and belief, Amneal, [redacted] knows that its ANDA Products will be used by doctors and patients for the treatment of ADHD and that when used, the ANDA Products will exhibit the properties described in the ANDA, [redacted]

70. On information and belief, Amneal, [redacted] knows that its ANDA Products will be used by doctors and patients for the treatment of ADHD, that its ANDA Products are especially made or adapted for use in accordance with its proposed label, and that its ANDA Products are not a staple or commodity of commerce suitable for substantial noninfringing use.

**REDACTED PUBLIC VERSION**

**COUNT I: INFRINGEMENT OF THE '798 PATENT**

71. Plaintiffs incorporate and reallege paragraphs 1 through 70 above, as if set forth in full herein.

72. On information and belief, the commercial manufacture, use, offer for sale, marketing, distribution, and/or importation into the United States of the ANDA Products is covered by the '798 Patent.

73. Amneal had knowledge of the '798 Patent when it submitted ANDA No. 207515, [redacted]

74. Amneal's submission of ANDA No. 207515, [redacted] for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, marketing, distributing, and/or importation of the ANDA Products before the expiration date of the '798 Patent is an act of infringement of the '798 Patent under 35 U.S.C. § 271(e)(2).

75. On information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of the ANDA Products will infringe one or more claims of the '798 Patent, including, for example and at least, claim 8.

76. On information and belief, the use of the ANDA Products in accordance with and as directed by the proposed labeling for the ANDA Products will infringe one or more claims of the '798 Patent, including, for example and at least, claim 8.

77. On information and belief, unless enjoined by this Court, Amneal plans and intends to engage in the manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of the ANDA Products and their proposed labeling immediately following the FDA's approval of ANDA No. 207515.

78. On information and belief, Amneal knew or was willfully blind to the fact that the ANDA Products and their proposed labeling are especially made or adapted for use in

infringing the '798 Patent given the standards for approval of generic drug products, and that the ANDA Products and their proposed labeling are not suitable for any substantial noninfringing use given that FDA regulates the distribution, marketing, and sale of drug products such as Amneal's ANDA Products..

79. On information and belief, Amneal, including by making and distributing the ANDA Products and their proposed labeling, intends to cause others to perform acts that Amneal knows will infringe one or more claims of the '798 Patent, including, for example and at least, claim 8.

80. On information and belief, unless enjoined by this Court, Amneal plans and intends to, and will, actively induce infringement of the '798 Patent immediately following the FDA's approval of ANDA No. 207515.

81. On information and belief, unless enjoined by this Court, Amneal plans and intends to, and will, contribute to the infringement of the '798 Patent immediately following the FDA's approval of ANDA No. 207515.

82. The foregoing actions by Amneal constitute, and/or will constitute, direct infringement of the '798 Patent, active inducement of others to infringe the '798 Patent, and/or contribution to the infringement by others of the '798 Patent.

83. On information and belief, Amneal acted without a reasonable basis for believing that it would not be liable for infringing the '798 Patent, actively inducing infringement of the '798 Patent, and/or contributing to the infringement of the '798 Patent.

84. Unless Amneal is enjoined from infringing the '798 Patent, actively inducing infringement of the '798 Patent, and/or contributing to the infringement of the '798 Patent, Plaintiffs will suffer irreparable injury.

85. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for

**REDACTED PUBLIC VERSION**

Amneal's ANDA No. 207515 to be a date which is not any earlier than the expiration date of the '798 Patent, including any extensions of that date.

86. Plaintiffs do not have an adequate remedy at law.

**COUNT II: INFRINGEMENT OF THE '549 PATENT**

87. Plaintiffs incorporate and reallege paragraphs 1 through 86 above, as if set forth in full herein.

88. On information and belief, the commercial manufacture, use, offer for sale, marketing, distribution, and/or importation into the United States of the ANDA Products is covered by the '549 Patent.

89. Amneal had knowledge of the '549 Patent when it submitted ANDA No. 207515, [redacted]

90. Amneal's submission of ANDA No. 207515, [redacted] for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, marketing, distributing, and/or importation of the ANDA Products before the expiration date of the '549 Patent is an act of infringement of the '549 Patent under 35 U.S.C. § 271(e)(2).

91. On information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of the ANDA Products will infringe one or more claims of the '549 Patent, including, for example and at least, claim 16.

92. On information and belief, the use of the ANDA Products in accordance with and as directed by the proposed labeling for the ANDA Products will infringe one or more claims of the '549 Patent, including, for example and at least, claim 16.

93. On information and belief, unless enjoined by this Court, Amneal plans and intends to engage in the manufacture, use, offer for sale, sale, marketing, distributing, and/or

importation of the ANDA Products and their proposed labeling immediately following the FDA's approval of ANDA No. 207515.

94. On information and belief, Amneal knew or was willfully blind to the fact that the ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '549 Patent given the standards for approval of generic drug products, and that the ANDA Products and their proposed labeling are not suitable for any substantial noninfringing use given that FDA regulates the distribution, marketing, and sale of drug products such as Amneal's ANDA Products.

95. On information and belief, Amneal, including by making and distributing the ANDA Products and their proposed labeling, intends to cause others to perform acts that Amneal knows will infringe one or more claims of the '549 Patent, including, for example and at least, claim 16.

96. On information and belief, unless enjoined by this Court, Amneal plans and intends to, and will, actively induce infringement of the '549 Patent immediately following the FDA's approval of ANDA No. 207515.

97. On information and belief, unless enjoined by this Court, Amneal plans and intends to, and will, contribute to the infringement of the '549 Patent immediately following the FDA's approval of ANDA No. 207515.

98. The foregoing actions by Amneal constitute, and/or will constitute, direct infringement of the '549 Patent, active inducement of others to infringe the '549 Patent, and/or contribution to the infringement by others of the '549 Patent.

99. On information and belief, Amneal acted without a reasonable basis for believing that it would not be liable for infringing the '549 Patent, actively inducing infringement of the '549 Patent, and/or contributing to the infringement of the '549 Patent.

**REDACTED PUBLIC VERSION**

100. Unless Amneal is enjoined from infringing the '549 Patent, actively inducing infringement of the '549 Patent, and/or contributing to the infringement of the '549 Patent, Plaintiffs will suffer irreparable injury.

101. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Amneal's ANDA No. 207515 to be a date which is not any earlier than the expiration date of the '549 Patent, including any extensions of that date.

102. Plaintiffs do not have an adequate remedy at law.

## RELIEF SOUGHT

**WHEREFORE**, Plaintiffs respectfully request the following relief:

A. The entry of judgment that the '798 Patent and the '549 Patent are valid and enforceable;

B. The entry of judgment that the '798 Patent and the '549 Patent would be directly infringed by the ANDA Products, either literally or under the doctrine of equivalents; that Amneal's submission of ANDA No. 207515, [redacted] is an act of infringement of the '798 Patent and the '549 Patent; and that Amneal's making, using, offering to sell, selling, marketing, distributing, or importing the ANDA Products, or any product that infringes the '798 Patent or the '549 Patent, prior to the dates that the '798 Patent and the '549 Patent expire, including any extensions of those dates, would infringe, actively induce infringement, and contribute to the infringement of the '798 Patent or the '549 Patent;

C. The entry of an order pursuant to 35 U.S.C. § 271(e)(4) directing the FDA to not approve Amneal's ANDA No. 207515, or any product or compound that infringes the '798 Patent or the '549 Patent, or, as the case may be, to not make the effective date of approval of

**REDACTED PUBLIC VERSION**

Amneal's ANDA No. 207515 any earlier than the dates that the '798 Patent and the '549 Patent expire, including any extensions of those dates;

D. The entry of a permanent injunction, enjoining Amneal, its officers, directors, agents, servants, employees, successors and assigns, and all others in concert and privity with them, from making, using, offering to sell, selling, marketing, distributing, or importing the ANDA Products, or any other products not colorably different, that infringe the '798 Patent or the '549 Patent, and from inducing or contributing to the infringement of the '798 Patent or the '549 Patent, until after the expiration of the '798 Patent or the '549 Patent, including any extensions of those dates;

E. Damages or other monetary relief, including prejudgment interest, if Amneal engages in the commercial manufacture, use, offering to sell, sale, marketing, distribution, or importation of the ANDA Products, or any other products that infringe the '798 Patent or the '549 Patent, or the inducement of or contribution to such infringement, prior to the expiration of '798 Patent or the '549 Patent, including any extensions of those dates;

F. The entry of judgment that, in view of Amneal's relevant acts, this case is an exceptional case under 35 U.S.C. § 285, entitling Plaintiffs to an award of their reasonable attorneys' fees for bringing and prosecuting this action;

G. An award of pre-judgment and post-judgment interest on each and every award;

H. An award of Plaintiffs' costs and expenses in bringing and prosecuting this action; and

I. Such other and further relief as the Court may deem just and proper.

**REDACTED PUBLIC VERSION**

ASHBY & GEDDES

*/s/ Steven J. Balick*

Steven J. Balick (#2114)
Andrew C. Mayo (#5207)
500 Delaware Avenue, 8th Floor
P.O. Box 1150
Wilmington, Delaware 19899
(302) 654-188
sbalick@ashby-geddes.com
amayo@ashby-geddes.com

*Attorneys for Plaintiffs*
*ALZA Corporation and*
*Janssen Pharmaceuticals, Inc.*

*Of Counsel:*

David T. Pritikin
SIDLEY AUSTIN LLP
One South Dearborn Street
Chicago, Illinois 60603
(312) 853-7000
dpritikin@sidley.com

Peter S. Choi
Fitz B. Collings
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, D.C. 20005
(202) 736-8000
peter.choi@sidley.com
fcollings@sidley.com

Dated: October 7, 2016